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Form Approved: OMB No. 0910-0498; Expiration Date: 3/31/09

Department of Health and Human Services
Food and Drug Administration

# SUPPLEMENTARY INFORMATION
# CERTIFICATE OF EXPORTABILITY REQUESTS

## 1. Requestor Information

| Name | Address |
|---|---|
| Firm | |
| Telephone number / FAX number / Firm Tax ID code / Email address | |

## 2. Manufacturer Information

| Firm | Address *(P.O. Box not acceptable)* |
|---|---|
| Registration number | Date of last FDA inspection |

## 3. Product Information

| Product name | Does the product have an approved IDE? |
|---|---|
| Product class: ☐ Class 1 ☐ Class 2 ☐ Class 3 | ☐ Yes ☐ No<br>If yes, provide IDE number: _____ |

## 4. List country(ies) for which the Certificates are requested.

## 5. Indicate what product information should appear on the certificate.

## 6. Should the country destination be listed on the certificate? (Note: CDRH does not list a specific country on a certificate.)

☐ Yes ☐ No Indicate the total number of certificates requested: _____

## 7. Are you exporting pursuant to section 801(e) or section 802 of the Act?

☐ To section 801(e) ☐ To section 802

**NOTE:** To meet the requirements for exporting products pursuant to section 802 of the Act, an exporter must maintain records of the product(s) exported and the countries to which they were exported. Notification of exporting unapproved drugs or devices, including biologics, pursuant to section 802(g) of the Act is separate from requesting or receiving a Certificate of Exportabilit. Notification to FDA is required when the exporter first begins to export and should be sent to the same address for requesting export certificates.


| | |
|---|---|
| ***CBER instructions begin on page 5.*** | ***CDRH instructions for 802 begin on page 9.*** |
| ***CDRH instructions for 801(e)(1) begin on page 6.*** | ***CVM instructions begin on page 13.*** |

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| Department of Health and Human Services<br>Food and Drug Administration | **EXPORTER'S CERTIFICATION STATEMENT**<br>***"CERTIFICATE OF EXPORTABILITY"***<br>***for CBER and CVM*** |
|---|---|

FIRM NAME

As the responsible official or designee of the company named above, I hereby certify to the United States Food and Drug Administration that:

- the product(s) accords to the specifications of the foreign purchaser;
- the product(s) is not in conflict with the laws of the country to which it is intended for export;
- the shipping package for the product(s) is labeled on the outside that it is intended for export; and
- the product(s) is not sold or offered for sale in the United States

(Check below, if exporting under Section 802 of the Act.)

☐ In addition, I hereby certify to the FDA that pursuant to Section 802(f)(1) of the Act, the product(s) being exported has been manufactured, processed, packaged, and held in substantial conformity with current good manufacturing practice requirements.

| SIGNATURE | DATE |
|---|---|

NAME AND TITLE

Making or submitting false statements on any documents submitted to FDA may constitute violations of the United States Code Title 18, Chapter 47, Section 1001 with penalties including up to $250,000 in fines and up to 5 years imprisonment.

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Department of Health and Human Services
Food and Drug Administration

# EXPORTER'S CERTIFICATION STATEMENT
## *"CERTIFICATE OF EXPORTABILITY"*
## *for CDRH [Section 801(e)(1)]*

**REQUESTING COMPANY**

As the responsible official or designee of the requesting company named above, I hereby certify to the Food and Drug Administration (FDA) that the company and the products identified on the attached application for a Certificate of Exportability [Section 801(e)(1)] are to the best of my knowledge in compliance with [Section 801(e)(1)] of the Federal Food, Drug, and Cosmetic Act (the Act) and all applicable or pertinent rgulations enforced by the FDA as follows:

1. Each product(s) identified for export accord to the specification of the foreign purchaser; 801(e)(1);
2. Each product(s) identified are not in conflict with the laws of the country to which it is intended for export; 801(e)(1)
3. The product(s) shipping package for the product(s) is labeled on the outside that it is intended for export; 801(e)(1); and
4. The product(s) is not sold or offered for sale in domestic commerce (the United States); 801(e)(1).
5. No HIV products are listed on this request.
6. No Class III products are listed on this request.

I hereby make this certification of compliance statement to FDA with full knowledge that the making or submission of false statements represent violations of United States Code Title 18, Chapter 47, Section 1001. Penalties include up to $250,000 in fines and up to five years imprisonment.

| SIGNATURE | DATE |
|---|---|
| | |

NAME AND TITLE

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Department of Health and Human Services
Food and Drug Administration

# EXPORTER'S CERTIFICATION STATEMENT
## *"CERTIFICATE OF EXPORTABILITY"*
## *for CDRH (Section 802)*

**REQUESTING COMPANY**

As the responsible official or designee of the requesting company named above, I hereby certify to the Food and Drug Administration (FDA) that the company and the products identified on the attached application for a Certificate of Exportability (Section 802) are to the best of my knowledge in compliance with Section 802 of the Federal Food, Drug, and Cosmetic Act (the Act) and all applicable or pertinent regulations enforced by the FDA as follows:

1. The requesting company is currently registered and has listed each of its medical devices identified for export as required by Section 510 of the Act and 21 CFR Part 807 (see attached Supplementary Information);

2. Each product(s) identified for export is manufactured substantially in accordance with good manufacturing practices or international quality systems standards recognized by the Secretary; 802(f)(1) (At this time, the Secretary has not recognized any international quality system standards,);

3. Each product(s) identified is not adulterated by containing any filthy, putrid or decomposed substance in whole or in part; 501(a)(1);

4. Each product(s) identified is not prepared, packed or held under insanitary conditions whereby it may be contaminated with filth or rendered injurious to health; 501(a)(2)(A);

5. Each product(s) container does not contain any poisonous or deleterious substance which may render the device injurious to health; 501(a)(3);

6. Each product(s) identified for export accords to the specification of the foreign purchaser; 801(e)(1);

7. Each product(s) identified is not conflict with the laws of the country to which it is intended for export; 801(e)(1);

8. The shipping package for the product(s) is labeled on the outside that it is intended for export; 801(e)(1);

9. The product(s) is not sold or offered for sale in domestic commerce (the United States); and 801(e)(1);

10. The product(s) identified is not an imminent hazard to health in the United States, as notified by the Secretary; 802(f)(4)(B); and

11. The product(s) identified are labeled in accordance with the requirements of the Tier 1 Country (country granting valid marketing authorization under 802(b)) that granted marketing authorization, as well as the requirements of any other country to which the device would be exported (including language requirements and units of measure), 802(f)(5);

12. The product(s) identified is promoted in accordance with labeling requirement of 802(f)(5); 802(f)(6).

13. No HIV products are listed on this request.

I hereby make this certification of compliance statement to FDA with full knowledge that the making or submission of false statements represent violations of United States Code Title 18, Chapter 47, Section 1001. Penalties include up to $250,000 in fines and up to five years imprisonment.

| SIGNATURE | DATE |
|---|---|
| | |

NAME AND TITLE

**Department of Health and Human Services**
**Food and Drug Administration**

# EXPORT CERTIFICATION

## *Submission Requirements for Requesting Certificates for Exporting Products to Foreign Countries (for CBER)*

## Background

Firms exporting products from the U.S. are often asked by foreign customers or foreign governments to supply a certification relating to products subject to the Federal Food, Drug, and Cosmetic Act and other acts the Food and Drug Administration (FDA) administers. Under the FDA Export Reform and Enhancement Act of 1996 (the Act), FDA is authorized to issue certificates for drugs, animal drugs, and devices within 20 days of receipt of a request for such a certificate. A fee of up to $175 may be charged for each certificate issued. In addition to issuing export certificates for approved or licensed products, the FDA will also issue export certificates for unapproved products that meet the requirements of Sections 801(e) or 802 of the Act.

## General Instructions:

- The **"Certificate to Foreign Government"** is for the export of products legally marketed in the United States. Certificate requests should include the information listed in **Supplementary Information – Certificate to Foreign Government Requests** *(PDF, Text)*. Please ensure that the Exporter's Certification Statement is signed by a responsible official of the exporting firm and is enclosed with the certificate request. Please ensure that the appropriate Exporter Certification Statements for Certificate to Foreign Government Requests for Human Cells, Tissues, and Cellular and Tissue-Based Products (procured prior to May 25, 2005, or on or after May 25, 2005) is signed by a responsible official of the exporting firm and is enclosed with the certificate request.

- The **"Certificate of Exportability"** is for the export of products not approved for marketing in the United States (unapproved products) that meet the requirements of Sections 801(e) or 802 of the Act. Certificate requests should include the information listed in **Supplementary Information - Certificate of Exportability Requests** *(PDF, Text)*. Please ensure that the Exporter's Certification Statement is signed by a responsible official of the exporting firm and is enclosed with the certificate request.

- The **"Certificate of a Pharmaceutical Product"** conforms to the format established by the World Health Organization(WHO) and is intended for use by the importing country when the product in question is under consideration for a product license that will authorize its importation and sale or for renewal, extension, amending or reviewing a license. WHO Certificate requests should include the information listed in **Supplementary Information – Certificate of a Pharmaceutical Product Requests** *(PDF, Text)*. Please ensure that the Exporter's Certification Statement is signed by a responsible official of the exporting firm and is enclosed with the certificate request.

- The **"Non-clinical Research Use Only Certificate** is for the export of a non-clinical research use only product, material, or component that is not intended for human use which may be marketed in, and legally exported from the United States under the Federal, Food, Drug and Cosemetic Act. Certificate requests should include the information listed in **Supplementary Information - Non-clinical Research Use Only Certificate Requests** *(PDF, Text)*. Please ensure that the Exporter's Certification Statement is signed by a responsible official of the exporting firm and is enclosed with the certificate request.

- Please type certificate requests or print clearly.

- In most cases, one product will be listed per certificate. However, products that were approved under the same PLA / BLA, NDA, PMA or 510(k) application or similar unapproved products may be listed on the same certificate based on the available space for a one page certificate. Certificate requests for listing multiple products will be evaluated on a case-by-case basis.

- If information is omitted in the application by the requester or if clarification is needed on the supplied information, the requester will be contacted via telephone or FAX. If the requester does not provide the necessary information within 48 hours, the request for certificates will be returned and will need to be resubmitted for FDA review.

- Questions may be directed to the Import/Export Team at 301-827-6201.

- Send the request and supporting documents to:

  Food and Drug Administration
  Center for Biologics Evaluation and Research
  Office of Compliance and Biologics Quality
  Division of Case Management
  1401 Rockville Pike, Attention: HFM-624
  Rockville, MD 20852-1448

  or via FAX at 301-594-0940

- On October 1, 1996, CBER was given the authority to charge $175 for the first two certificates and $85 for any subsequent certificates issued for the same product(s) in response to the same certificate request. Please do not submit a check with your request, as FDA will bill you quarterly for issued certificates.

- You may enclose a completed FEDEX form to expedite the return of Certificates.

**Issuance of a "Certificate to Foreign Government", "Certificate of Exportability" or "Certificate of a Pharmaceutical Product" will not preclude regulatory action by FDA, if warranted, against products covered by the Certificate.**

**A "Certificate to Foreign Government", "Certificate of Exportability" or "Certificate of a Pharmaceutical Product" is issued by FDA solely for export purposes and may not be used for domestic advertising.**

**Department of Health and Human Services**
**Food and Drug Administration**

# INSTRUCTIONS FOR REQUESTS FOR CERTIFICATE OF EXPORTABILITY [Section 801(e)(1)]

## *(for CDRH)*

1. Complete the "Exporter's Certification Statement" and the "Supplementary Information Sheet." Please ensure that you sign the Exporter's Certification Statement.

2. Using the attached example **(Attachment D)**, prepare on plain white 8 ½" x 11" bond paper, the Certificate of Exportability [Section 801(e)(1)] **(print margin one inch, top margin one inch, 44 lines per page)**. You may also submit this information on a standard IBM compatible 3 ½" diskette using Word Perfect 5.1 or Microsoft Word software. Diskettes received will be scanned for viruses using an anti-virus scanning program. In addition, diskettes submitted will not be returned.

3. If more than three products to be included on the Certificate, provide a typed list of products on consecutively numbered 8 ½" x 11" sheets of paper **(Attachment E)**. Do not submit catalogs or catalog pages.

4. Effective July 1, 1999, each request is limited to a total of 100 pages, including the Certificate and Attachment Page(s). If your need exceeds the 100 page limit, you must request additional certificates. For example, if you request a certificate with 9 attachment pages (for a total of 10 pages), you may request up to 1 original and 9 subsequent certificates.

5. Enclose a self-addressed stamped envelope or FEDEX envelope large enough to accommodate the requested Certificate(s).

6. Send the request and supporting documents to:

   Food and Drug Administration
   Center for Devices and Radiological Health
   Office of Compliance
   Attention: HFZ-307
   9200 Corporate Boulevard
   Rockville, MD 20850

7. Clearly mark on the outside of the envelope containing the request as a "Request for Certificates." If you have any questions, please call 240 276-0132.

8. We do not certify Foreign Manufacturers; therefore, please provide the name and address of the U.S. Initial Distributor **(P.O. Box not acceptable)**.

9. As of March 1, 2003, CDRH has the authority to charge $175 for the first certificate and $15 for any subsequent certificates issued for the same product(s) in response to the same request. **Please do not submit a check with your request, as FDA will bill you quarterly.**

10. If information is omitted in the application by the requester or if clarification is needed on the supplied information, the requester will be contacted via email, telephone, or FAX. If the requester does not provide the necessary information within 48 hours, the request for certificates will be returned and will need to be resubmitted for FDA review.

11. Issuance of a "Certificate to Foreign Government" or "Certificate of Exportability" will not preclude regulatory action by FDA, if warranted, against products covered by the Certificate.

12. A "Certificate to Foreign Government" or "Certificate of Exportability" is issued by FDA solely for export purposes and may not be used for domestic advertising.

***ATTACHMENT D***

**E X A M P L E**

Certificate No.

## CERTIFICATE OF EXPORTABILITY [SECTION 801(e)(1)]

The Food and Drug Administration certifies that the product(s) described below is subject to it jurisdiction under the Federal Food, Drug, and Cosmetic Act (the Act). The products described below may not be sold or offered for sale in the United States. The company has certified to the Food and Drug Administration that:

- the product(s) accords to the specifications of the foreign purchaser;
- the product(s) is not in conflict with the laws of the country to which it is intended for export;
- the shipping package for the product(s) is labeled on the outside that it is intended for export; and
- the product(s) is not sold or offered for sale in the United States.

Based on the information above, the product(s) listed below may be exported pursuant to Section 801(e)(1) of the Act.

**NAME OF PRODUCT(S)**
**(GENERIC NAME IF APPLICABLE)**

**NAME OF COMPANY, ADDRESS**

Regulatory Policy and Systems Branch
Office of Compliance
Center for Devices and Radiological Health

**This certificate expires 24 months from the date notarized.**

COUNTY OF MONTGOMERY
STATE OF MARYLAND

Subscribed and sworn to before me this _____ day of _____ month _____ year.

_____
*Signature*

***ATTACHMENT E***

## EXAMPLE OF ATTACHMENT PAGE(S)

Format should be "Page # of Total pages

Certificate of Exportability [Section 801(e)(1)] – Attachment (Page # of # Pages)

| Name of Product(s) (Generic name if applicable) | Name of Company, Address |
|---|---|
| Arterial Fixation | ABC, Inc.<br>909 Glebe Road<br>Winter Haven, FL 33844 |
| Mamary Prosthesis | |
| Knee Cup | |
| Penile Implant | |
| Arterial Filter with air separation chamber | |
| Arterial Filter with Biothyl coating | |
| "END OF PRODUCT LIST" | |

Please list company name and address on all attachment pages

List all product(s) separately and state associated devices

Please place this state-ment at the end of your product

Paper Type: Plain White
8-1/2" x 11" Bond

Margins: Top 1"
Left 1"
Right 1"
Bottom 1"

Lower Right Corner 2-1/2" (to allow for gold seal)

Gold Seal

**Note: Please list as many products on each page as possible, minimum Font size 9.**

**Department of Health and Human Services**
**Food and Drug Administration**

# INSTRUCTIONS FOR REQUESTS FOR CERTIFICATE OF EXPORTABILITY (SECTION 802)

## *(for CDRH)*

1. Complete the "Exporter's Certification Statement" and the "Supplementary Information Sheet." Please ensure that you sign the Exporter's Certification Statement.

2. Using the attached example **(Attachment F)**, prepare on plain white 8 ½" x 11" bond paper, the Certificate of Exportability (Section 802) **(print margin one inch, top margin one inch, 44 lines per page)**. You may also submit this information on a CD or disk using Microsoft Word or compatible software.

3. If more than three products to be included on the Certificate, provide a typed list of products on consecutively numbered 8 ½" x 11" sheets of paper **(Attachment G)**. Do not submit catalogs or catalog pages.

4. Effective July 1, 1999, each request is limited to a total of 100 pages, including the Certificate and the Attachment Page(s). If your need exceeds the 100 page limit, you must request additional certificates. For example, if you request a certificate with 9 attachment pages (for a total of 10 pages), you may request up to 1 original and 9 subsequent certificates **(10 Certificates)**.

5. Enclose a self-addressed stamped envelope or FEDEX envelope large enough to accommodate the requested Certificate(s).

6. Send the request and supporting documents to:

   Food and Drug Administration
   Center for Devices and Radiological Health
   Office of Compliance
   Attention: HFZ-307
   9200 Corporate Boulevard
   Rockville, MD 20850

7. Clearly mark on the outside of the envelope containing the request as a "Request for Certificates." If you have any questions, please call 240 276-0132 or email *exportcert@cdrh.fda.gov*.

8. We do certify Foreign Manufacturers, if they have been inspected by FDA, and this inspection was acceptable. Please provide the name and address of the U.S. Initial Distributor **(P.O. Box not acceptable),** for billing purposes. Also, U.S. Initial Distributor must be listed on Certificate no exception.

9. As of March 1, 2003, CDRH has the authority to charge $175 for the first certificate and $15 for any subsequent certificates issued for the same product(s) in response to the same request. **Please do not submit a check with your request, as FDA will bill you quarterly.**

10. The Certificate of Exportability (Section 802) **[Attachment F]** may be copied and used for subsequent shipments, as long as an original Foreign Country Certification Statement **(Attachment H)** is attached. **Note:** FDA will not authenticate copy of a certificate.

11. If information is omitted in the application by the requester or if clarification is needed on the supplied information, the requester will be contacted via email, telephone, or FAX. If the requester does not provide the necessary information within 48 hours, the request for certificates will be returned and will need to be resubmitted for FDA review.

12. Issuance of a "Certificate to Foreign Government" or "Certificate of Exportability" will not preclude regulatory action by FDA, if warranted, against products covered by the Certificate.

13. A "Certificate to Foreign Government" or "Certificate of Exportability" is issued by FDA solely for export purposes and may not be used for domestic advertising.

***ATTACHMENT F***

**E X A M P L E**

Certificate No.

## CERTIFICATE OF EXPORTABILITY (SECTION 802)

The Food and Drug Administration certifies that the product(s) described below is subject to it jurisdiction under the Federal Food, Drug, and Cosmetic Act (the Act). Such product(s), which is not approved for marketing in the United States, may be legally exported provided it meets the requirements of Section 802 of the Act.

Under Section 802 of the Act, a drug or device not approved for marketing in the United States may be exported if it is manufactured, processed, packaged, and held in substantial conformity with current good manufacturing practice requirements. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed below. The company has certified to the Food and Drug Administration that:

- ❖ the product(s) accords to the specifications of the foreign purchaser;
- ❖ the product(s) is not in conflict with the laws of the country to which it is intended for export;
- ❖ the shipping package for the product(s) is labeled on the outside that it is intended for export; and
- ❖ the product(s) is not sold or offered for sale in the United States.

Based on the information above, the product(s) listed below may be exported pursuant Section 802 of the Act.:

| **NAME OF PRODUCT(S) (GENERIC NAME IF APPLICABLE)** | **MANUFACTURING LOCATION** |
|---|---|

Regulatory Policy and Systems Branch
Office of Compliance
Center for Devices and Radiological Health

**This certificate expires 24 months from the date notarized.**

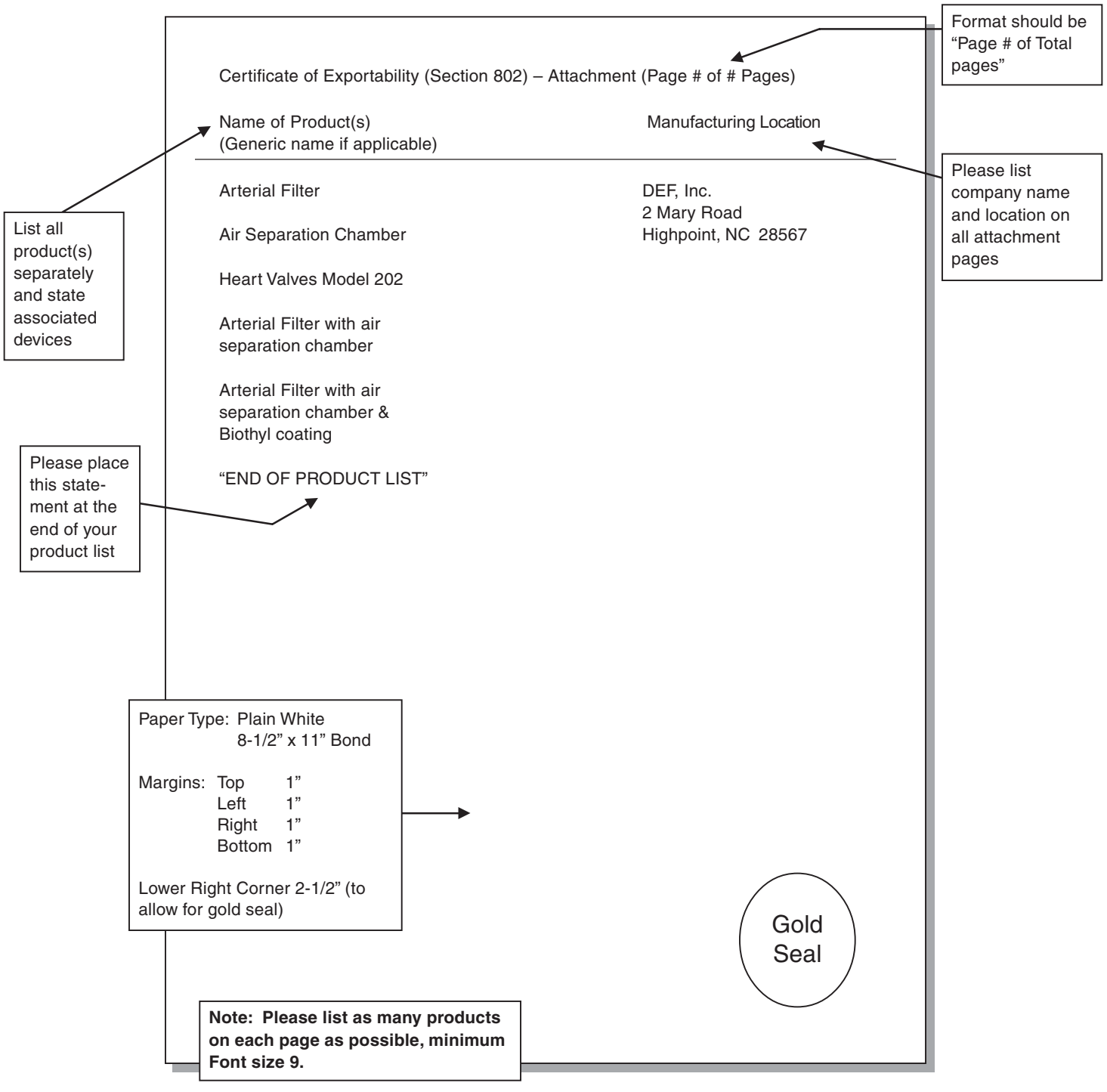
COUNTY OF MONTGOMERY
STATE OF MARYLAND

_____
*Signature*

Subscribed and sworn to before me this _____ day of _____ month _____ year.

***ATTACHMENT G***

## EXAMPLE OF ATTACHMENT PAGE(S)



***ATTACHMENT H***

## FOREIGN COUNTRY CERTIFICATION STATEMENT

As a responsible official of _____, I hereby certify that the company and products identified in the attached Certificate of Exportability (Section 802) continue to be, to the best of my knowledge, in compliance with the Federal Food, Drug, and Cosmetic Act and all applicable or pertinent regulations enforced by the U.S. Food and Drug Administration. A Photocopy of the Certificate of Exportability (Section 802) may be used as long as this original statement is attached..

_____
Signature

_____
Typed Name and Title

Subscribed and sworn to before me this _____ day of _____ month _____ year.

**Department of Health and Human Services**
**Food and Drug Administration**

# INSTRUCTIONS FOR COMPLETION OF APPLICATION FOR CERTIFICATES

## *(for CVM)*

1. The Export Certificate to Foreign Governments is for the export of products legally marketed in the United States. An application form must be completed and signed. The form is to be completed by the responsible head or designee of the exporting firm. Please enclose labels for each product.

2. The Certificate of Exportability is for the export of products unapproved for distribution and sale in the United States. The requestor must meet the requirements of Section 801(e) of the Act.

3. The **"Certificate of a Pharmaceutical Product"** conforms to the format established by the World Health Organization(WHO) and is intended for use by the importing country when the product in question is under consideration for a product license that will authorize its importation and sale or for renewal, extension, amending or reviewing a license. WHO Certificate requests should include the information listed in **Supplementary Information – Certificate of a Pharmaceutical Product Requests**. Please ensure that the Exporter's Certification Statement is signed by a responsible official of the exporting firm and is enclosed with the certificate request.

4. If the requested information on the application form is not provided by the exporting firm or if clarification is needed on the supplied information, the exporting firm will be contacted via telephone or FAX. If the exporting firm does not provide the necessary information within 48 hours, the request for certificates will be returned and will need to be resubmitted. You may enclose a completed FEDEX form to expedite return of the Certificates. A certificate will be issued for each product.

5. Requests for certificates should be sent to:

   Kim Bell
   Center for Veterinary Medicine Division of Compliance (HFV-235)
   7519 Standish Place
   Rockville, MD 20855

   (240-276-9212- for inquiries)

6. The fee for preparing and issuing a single certificate is $175; 1st duplicate original $155 and $70 for each subsequent duplicate. No fee will be charged for animal food/feed products. Please do not include the fee payment with your requests; the exporting firm will be billed quarterly.

7. The instructions and applications will be available on the *CVM Home Page (www.fda.gov/cvm/exportcertificate.htm)*.

**PLEASE NOTE: Making or submitting false statements on any documents submitted to FDA represents violations of the United States Code, Title 18, Chapter 47, Section 1001 with penalties including up to $10,000 in fines and up to 5 years imprisonment.**

**Issuance of an Export Certificate for Approved Products or Certificate of Exportability will not preclude regulatory action by FDA, if warranted, against products covered by the Certificate. Certificates issued by the FDA are solely for export purposes and may not be used for domestic advertising.**

***Paperwork Reduction Act Statement***

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the applicable address below.

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20857

Food and Drug Administration
Center for Devices and Radiological Health (HFZ-307)
9200 Corporate Boulevard
Rockville, MD 20850

Food and Drug Administration
Center for Veterinary Medicine (HFV-235)
Division of Compliance
7519 Standish Place
Rockville, MD 20855

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.*